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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOEL R. STUDIN

Appeal 2009-013624¹
Application 10/829,316
Technology Center 1600

Before CAROL A. SPIEGEL, TONI R. SCHEINER, and STEPHEN WALSH,
Administrative Patent Judges.

SCHEINER, *Administrative Patent Judge.*

DECISION ON APPEAL²

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1-16 and 30-32 on the ground of obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

¹ Heard September 16, 2010.

² The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” (paper delivery mode) or the “NOTIFICATION DATE” (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

Claims 1, 30 and 31 are representative of the subject matter on appeal:

1. A method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars comprises: applying onto a healed wound a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane juxtaposed to the healed wound thereby reducing scarring or improving the appearance thereof.

30. A method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars comprises: applying onto a healed wound a topical composition comprising collagenase.

31. The method of claim 30, wherein said topical composition comprises collagenase contained within a fluid, film-forming carrier, subsequent to applying said composition onto said healed wound, hardening said carrier into a tangible membrane juxtaposed to the healed wound.

Claims 1-16 and 30-32 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Youssefeyeh³ and Lee.⁴

In addition, claims 1-16 and 30-32 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Mantelle⁵ and Lee.

We reverse.

FINDINGS OF FACT

1. Youssefeyeh discloses a method and topical composition for “reducing inflammation that triggers the onset of rheumatic diseases, eczema, urticaria, psoriasis, erythema multiforme and lichen planus;

³ U.S. Patent 5,968,519, issued October 19, 1999 to Youssefeyeh et al.

⁴ U.S. Patent 5,552,162, issued September 3, 1996 to Lee.

⁵ U.S. Patent 5,446,070, issued August 29, 1995 to Mantelle.

inflammation of the gums, and chronic localized body pain derived from acute injury” (Youssefeyeh, col. 1, ll. 13-16).

2. Youssefeyeh’s topical composition comprises “finely divided powder of safflower seed” in “a water-penetrable bag or container to be used in water, ointments, creams, lotions, solutions, dressings and patches, slow-release preparations and film-forming preparations” (Youssefeyeh, col. 13, ll. 64-65; col. 14, ll. 22-25). The composition may further comprise anti-inflammatory analgesics and corticosteroids (*id.* at col. 14, ll. 28-40).

3. Mantelle discloses “a method for the topical administration of an anesthetic agent or a combination of anesthetic agents to prevent or ameliorate pain” (Mantelle, col. 1, ll. 24-27). In addition, Mantelle discloses that any one of thousands of pharmaceutically active agents, including collagenase, can be substituted for the anesthetic agent (*id.*, at col. 23, ll. 33-36; col. 38, l. 4).

4. Mantelle teaches that “the incorporation of one or more anesthetic agents in a solvent for the anesthetic agent into a flexible, finite, pharmaceutically acceptable carrier, permits an exceptionally high loading of anesthetic agent in the carrier, permitting more rapid delivery of the anesthetic agent to the tissue” (Mantelle, col. 3, ll. 47-52).

5. According to Mantelle, “finite carriers” are “non-spreading substances which retain their form, e.g. patches, dressings and bandages” (Mantelle, col. 1, ll. 54-56).

6. Lee discloses “a method for improving the size and appearance of a scar by stimulating collagenase activity in the scar[,]” particularly “scars associated with a fibromatosis, keloid, or a hypertrophic wound healing disorder” (Lee, col. 6, ll. 11-16).

7. Lee's method is "based upon creating a set of conditions which are effective in bringing about an increase in the activity of the protease enzymes which occur naturally in human fibroblast scar tissue" (Lee, col. 8, ll. 6-9). Specifically, Lee's method stimulates endogenous collagenase activity "by elevating the surface temperature of the scar from about 0.5°C to about 5°C . . . by covering the scar with a thermal insulating material" such as a hydrogel (*id.* at col. 6, ll. 22-33).

DISCUSSION

Obviousness over Youssefyeh and Lee

The Examiner finds that Youssefyeh "explicitly teaches methods for treating inflammatory dermal conditions, both acute and chronic" (Ans. 5), thus, "[t]he methods of treatment and conditions to be treated as taught by Youssefyeh would include application upon healed wounds so as to reduce scarring and/or improve the appearance thereof" (*id.* at 6). In addition, the Examiner finds that "collagenase is provided in [Lee's] composition in order for the effective breakdown and degradation of collagen" (*id.*). Based at least in part on these findings, the Examiner concludes that "[i]t would have been obvious to one of ordinary skill in the art . . . to provide for methods for treating scars, such as hypertrophic scars such as taught by Lee within the methods of Youssefyeh" (*id.*).

Appellant contends that "the treatment of inflammation and pain associated with inflammatory dermatoses, gingivitis and acute injury, as taught and disclosed in Youssefyeh et al., is not the same as treating healed wounds so as to reduce scarring and/or improve the appearance of scars, as presently claimed" (App. Br. 4-5 (emphasis omitted)). Appellant contends "[t]here is simply no indication whatsoever in Youssefyeh et al. that the

composition disclosed therein can be used to treat healed wounds to reduce scarring or improve the appearance of scars” (*id.* at 7 (emphasis omitted)), thus “[t]here is simply no reason to combine elements of the composition disclosed in Youssefyeh . . . with elements of . . . Lee” (*id.* (emphasis omitted)). Moreover, with respect to claims 30-32, Appellant contends “there is no mention or suggestion whatsoever in Lee of including collagenase in a composition for treating and/or reducing scarring, as presently claimed” (*id.* at 9).

Given these conflicting positions, the principle issue raised by this appeal is whether the Examiner’s conclusion is based on an interpretation of the references that is not supported by the record. If so, the succeeding issue is whether the Examiner has otherwise established that it would have been obvious for one of ordinary skill in the art to apply a fluid, film-forming carrier to a healed wound, or to apply collagenase to a healed wound, with or without a film-forming carrier.

We agree with Appellant that the Examiner’s conclusion is based on at least two findings not supported by the record. Specifically, the Examiner has not provided any evidence to support the finding that any of the conditions and/or inflamed lesions treated by Youssefyeh would have been considered a “healed wound.” Nor does the evidence of record support the Examiner’s finding that Lee discloses applying collagenase to a healed wound. Rather, Lee discloses stimulating the activity of the collagenase “which occur[s] naturally in human fibroblast scar tissue” (FF7). In any case, the mere assertion that it would have been obvious “to provide for methods for treating scars . . . such as taught by Lee within the methods of Youssefyeh” (Ans. 6) does not explain how or why one of ordinary skill in

the art would have combined aspects of the references in the manner required by the claims.

Thus, the Examiner has not established that it would have been obvious to apply a fluid, film-forming carrier to a healed wound to form a tangible membrane juxtaposed to the wound. Nor has the Examiner established that it would have been obvious to apply collagenase to a healed wound, with or without a film-forming carrier.

Obviousness over Mantelle and Lee

The Examiner finds that Mantelle “teaches flexible, finite, bioadhesive compositions and methods for topical application comprising a therapeutically effective amount of a pharmaceutical agent(s), [including collagenase,] a pharmaceutically acceptable carrier and a solvent for the pharmaceutical agent(s) in the carrier” (Ans. 12). The Examiner finds that Mantelle “does not explicitly teach treatment of ‘healed wounds’ . . . [but] nonetheless explicitly teaches compositions that are topically applied on the skin for effective treatment of pain” (Ans. 12). The Examiner finds that Lee teaches “a method for improving the size and appearance of a scar associated with fibromatosis, a keloid or a hypertrophic wound healing disorder that comprises stimulating collagenase activity in the scar . . . [by] covering the scar with a hydrogel or thermally insulating material that elevates the surface temperature of the scar” (*id.* at 13). The Examiner concludes that “[i]t would have been obvious to one of ordinary skill in the art . . . to provide for methods for treating scars . . . such as taught by Lee within the methods of Mantelle” (*id.*).

Appellant contends “there is no mention or suggestion whatsoever in Mantelle that the composition disclosed therein can be used for treating a healed wound so as to reduce and/or improve the appearance of scarring” (App. Br. 11 (emphasis omitted)), while “Lee does not teach or suggest the use of a fluid, film-forming carrier and hardening the carrier into a tangible membrane juxtaposed to the healed wound” (*id.* (emphasis omitted)). Appellant contends “[t]here is simply no reason to combine the elements of the composition disclosed in Mantelle with elements of the composition disclosed in Lee” (*id.* at 12 (emphasis omitted)).

The issue raised by this appeal is whether the Examiner has established that it would have been obvious for one of ordinary skill in the art to apply a fluid, film-forming carrier to a healed wound, or to apply collagenase to a healed wound, with or without a film-forming carrier, given the teachings of Mantelle and Lee.

Mantelle, which is primarily directed to topical administration of anesthetic agents to prevent or ameliorate pain (FF3), is no more relevant to the claimed invention than Youssefyeh, discussed above. Moreover, the Examiner has not established that Mantelle discloses administering the agent in the form of a fluid, film-forming carrier, and subsequently hardening the carrier in to a tangible membrane (FF4). Again, the mere assertion that it would have been obvious “to provide for methods for treating scars . . . such as taught by Lee within the methods of Mantelle” (Ans. 13) does not explain how or why one of ordinary skill in the art would have combined aspects of the references in the manner required by the claims.

SUMMARY

The rejection of claims 1-16 and 30-32 under 35 U.S.C. § 103(a) as unpatentable over Youssefyeh and Lee is reversed.

The rejection of claims 1-16 and 30-32 under 35 U.S.C. § 103(a) as unpatentable over Mantelle and Lee is reversed.

REVERSED

dm

STUART D. FRENKEL
SUITE 330
3975 UNIVERSITY DRIVE
FAIRFAX, VA 22030